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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,054

12/15/2003

Philipp Kapranov

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08/01/2006

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,054

Applicant(s)

KAPRANOV ET AL.

Examiner

Angela Bertagna

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/6/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6 and 8-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Kapranov et al. (Science (May 3, 2002) 296: 916-919; cited in IDS filed 4/6/2005) as evidenced by the following: (a) the Supplemental References posted online with the article (see attached 2 pages from ftp://ftp1.nci.nih.gov/pub/CGAP/transcriptome/sci_21_22_paper/rawdata.html) and also the attached 8 pages obtained from <http://www.sciencemag.org/cgi/content/full/296/5569/916/DC1>) and (b) the Affymetrix Probe Design and Selection information (see the attached one page obtained from <http://www.affymetrix.com/technology/design/index.affx>).

Regarding claim 1, Kapranov teaches a method of determining small RNA transcriptional activity (see abstract) comprising:

- (a) obtaining a small RNA sample (p. 917, col. 1);

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(b) hybridizing the small RNA or nucleic acids derived from the RNA with an oligonucleotide probe array (p. 917, col. 1), wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes (p. 917, col. 1 – col. 2; see also Table 2 on p. 919), each of the perfect match probes targeting a different transcript sequence from a region of a genome (p. 917, col. 1 – col. 2);

(c) determining that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (p. 917, col. 1).

Regarding claim 2, Kapranov teaches that the region is at least 20 MB (see page 917, col. 1, where 35 million base pairs are analyzed).

Regarding claim 3, the Chrom 21_22 array used by Kapranov et al. (p. 917, col. 2) targets a region of the human genome greater than 50 MB (see page 1 of the supplementary material (2 page reference), section “Chromosomes 21 and 22”, which states that the region targeted is 70MB).

Regarding claims 4-6, the Chrom 21_22 array used by Kapranov targets the 70MB of chromosomes 21 and 22 (see page 1 cited above). Of this 70MB of sequence, about half (50%) is non-repetitive (page 1, “Chromosomes 21 and 22” section). Since the probes of Kapranov targeted the non-repetitive portions (p. 917, col. 1-2), the region of the genome targeted by Kapranov is 50%, and therefore, anticipates the instant claims 4 and 5, where the region of the genome is 25% or 50% of the sequences in a chromosome, respectively.

Regarding claims 8-11, Kapranov teaches that the probes target the transcript sequences from the genome at a resolution 1 bp (page 918, col. 1), thereby anticipating the instant claims 8-

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11, where a resolution of at least 100 bps, at least 30 bps, at least 10 bps, and 1 bp is claimed, respectively.

Regarding claim 12, Kapranov teaches isolation of RNA from nuclei (page 1, 2nd paragraph of the attached 8 page supplementary material reference).

Regarding claim 13, Kapranov teaches isolation of the small RNA sample from the cytoplasm (page 917, column 1).

Regarding claims 14-16, Kapranov teaches an array of 1,011,768 probes each targeting a different region of the genome (p. 917, col. 2), thereby anticipating the instant claims that the array contains at least 100,000 oligonucleotide probes, at least 500,000 oligonucleotide probes, and at least 800,000 oligonucleotide probes, respectively.

Regarding claims 17 and 18, Kapranov et al. used the Affymetrix Chrom 21_22 and DGCR arrays to analyze small RNA samples (p. 917, columns 1-2). Kapranov teaches that the arrays contain perfect match (PM) probes and also mismatch (MM) probes, but do not teach that the mismatch is a single mismatch in the middle of the probe. The Affymetrix printout cited above states, “ For each probe on the array that perfectly matches its target sequence, Affymetrix also builds a paired “mismatch” probe. The mismatch probe contains a single mismatch located directly in the middle of the 25-base probe sequence.” (paragraph 3 of the attached reference from Affymetrix). Therefore, Kapranov anticipates claims 17 and 18.

Regarding claim 19, Kapranov teaches that the perfect match probes are targeting transcripts from non-repetitive sequence of the genome (page 917, col. 1-2).

Regarding claim 20, Kapranov teaches a method for comparing the small RNA transcriptional activity of two biological samples comprising:

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- (a) obtaining a first small RNA sample (p. 917, col. 1);
- (b) obtaining a second small RNA sample (p. 917, col. 1);
- (c) hybridizing the first and second small RNA samples or nucleic acids derived from the first and second small RNA with an oligonucleotide probe array wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes (p. 917, col. 1-2), each of the perfect match probes targeting a different transcript sequence from a region of a genome (p. 917, col. 1);
- (d) determining, for each of the first and second sample, that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (p. 917, col. 1);
- (e) comparing the transcribed sequences between the first and second sample (page 917, col. 1 – page 918, col. 1; see also Tables 1 & 2 on p. 919).

3. Claims 1-16, 19, and 20 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Shoemaker et al. (US 2002/0045169 A1; published April 18, 2002). Regarding the 102(e) rejection, the Shoemaker pre-grant publication obtains benefit of the prior-filed Provisional Applications 60/227,966 and 60/227,902, both filed August 25, 2000.

Regarding claim 1, Shoemaker teaches a method of determining small RNA transcriptional activity comprising:

- (a) obtaining a small RNA sample (see paragraph 15; see also paragraph 88, where targets consisting of total RNA inherently contain small RNAs);
- (b) hybridizing the small RNA or nucleic acids derived from the RNA with an oligonucleotide probe array, wherein the oligonucleotide probe array contains at least 10,000

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perfect match (PM) probes, each of the perfect match probes targeting a different transcript sequence from a region of a genome (paragraph 94 teaches array hybridization; paragraph 67 teaches that the array has at least 10,000 complementary (or “perfect match” probes) targeting different transcripts from a genome)

(c) determining that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (paragraph 67).

Regarding claims 2-7, Shoemaker teaches that the probes on the array “sequentially tile” across an organism’s genome (paragraph 64). Shoemaker further teaches in Example 6 (paragraphs 178-179) an array designed to scan the entire human genome. Since the human genome is 3×10^9 bases (3,000 MB), the array of Shoemaker spans a region of the genome that is at least 20 MB, at least 50 MB, 25% of the DNA sequences in a chromosome, 50% of the DNA sequences in a chromosome, or the DNA sequence from the entire genome. The array of Shoemaker inherently includes DNA from a chromosome.

Regarding claims 8-11, Shoemaker teaches that the probes target the transcript sequences from the genome at a resolution of 1 bp (paragraph 66), thereby anticipating the instant limitations that the resolution be at least 100 bp, at least 30 bp, at least 10 bp, and 1 bp, respectively.

Regarding claims 12 and 13, Shoemaker teaches that the small RNA sample is obtained from the nuclei or the cytoplasm (see paragraph 88 where total RNA (which inherently includes nuclear and cytoplasmic RNA) and cytoplasmic RNA targets are taught).

Regarding claims 14-16, Shoemaker teaches that an oligonucleotide probe array containing 1,090,408 probes (paragraph 179 in Example 6), thereby anticipating the instant

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limitations that the array contain at least 100,000 oligonucleotide probes, at least 500,000 probes, or at least 800,000 probes, each targeting a transcript sequence from a different region of a genome.

Regarding claim 19, Shoemaker teaches that the perfect match probes target transcripts from non-repetitive sequence of the genome (paragraph 81).

Regarding claim 20, Shoemaker teaches a method for comparing the small RNA transcriptional activity of two biological samples comprising:

(a) obtaining a first small RNA sample (see paragraph 15; see also paragraph 88, where targets consisting of total RNA inherently contain small RNAs)

(b) obtaining a second small RNA sample (paragraph 127 teaches comparison of samples)

(c) hybridizing the first and second small RNA samples or nucleic acids derived from the first and second small RNA with an oligonucleotide probe array wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes, each of the perfect match probes targeting a different transcript sequence from a region of a genome (paragraph 94 teaches array hybridization; paragraph 67 teaches that the array has at least 10,000 complementary (or “perfect match” probes) targeting different transcripts from a genome; see also paragraph 127)

(d) determining, for each of the first and second sample, that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (paragraphs 67 and 127)

(e) comparing the transcribed sequences between the first and second sample (see paragraph 127).

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4. Claims 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Huttenhofer (EMBO Journal (2001) 20(11): 2943-2953).

Regarding claim 1, Huttenhofer teaches a method of determining small RNA transcriptional activity (page 2944) comprising:

- (a) obtaining a small RNA sample (page 2944, 1st paragraph in col. 1);
- (b) hybridizing the small RNA or nucleic acids derived from the RNA with an oligonucleotide probe array (p. 2944, last paragraph in col. 1), wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes (p. 2944, last paragraph in col. 1), each of the perfect match probes targeting a different transcript sequence from a region of a genome (p. 2944, last paragraph in col. 1);
- (c) determining that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (p. 2944, last paragraph in col. 1).

Regarding claim 20, Huttenhofer teaches a method for comparing the small RNA transcriptional activity of two biological samples comprising:

- (a) obtaining a first small RNA sample (p. 2944, col. 1, the Fraction I sample);
- (b) obtaining a second small RNA sample (p. 2944, col. 1, the Fraction II sample);
- (c) hybridizing the first and second small RNA samples or nucleic acids derived from the first and second small RNA with an oligonucleotide probe array wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes (p. 2944, last paragraph in column 1), each of the perfect match probes targeting a different transcript sequence from a region of a genome (p. 2944, last paragraph in col. 1);

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(d) determining, for each of the first and second sample, that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (p. 2944, last paragraph in col. 1);

(e) comparing the transcribed sequences between the first and second sample (p. 2944, last paragraph in col. 1).

5. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Gingeras (US 2003/0157529 A1). This pre-grant publication obtains benefit of the prior-filed Provisional Application 60/339,655, filed December 11, 2001.

The applied reference has a common inventor (Gingeras) and assignee (Affymetrix) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Gingeras teaches a method of determining small RNA transcriptional activity comprising:

(a) obtaining a small RNA sample (paragraph 7; the total RNA sample inherently contains small RNA);

(b) hybridizing the small RNA or nucleic acids derived from the RNA with an oligonucleotide probe array, wherein the oligonucleotide probe array contains at least 10,000

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perfect match (PM) probes, each of the perfect match probes targeting a different transcript sequence from a region of a genome (paragraph 7)

(c) determining that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (paragraph 7).

Regarding claims 2-7, Gingeras teaches that the region of the genome is at least 20 MB, at least 50 MB, 25% of the DNA sequences in a chromosome, 50% of the DNA sequences in a chromosome, DNA from a chromosome, or the DNA sequence from the entire genome (paragraph 8).

Regarding claims 8-11, Gingeras teaches that the probes target the transcript sequences from the genome at a resolution of at least 100 bps, at least 30 bps, at least 10 bps, or 1 bp (paragraph 9).

Regarding claims 12 and 13, Gingeras teaches that the small RNA sample is obtained from the nuclei or the cytoplasm (paragraph 7 and also paragraph 10).

Regarding claims 14-16, Gingeras teaches that the oligonucleotide probe array contains at least 100,000 oligonucleotide probes, at least 500,000 probes, or at least 800,000 probes, each targeting a transcript sequence from a different region of a genome (paragraph 11).

Regarding claims 17 and 18, Gingeras teaches that oligonucleotide array further comprises mismatch (MM) probes, wherein each of the mismatch probes is different from a perfect match probe in one base, and further that the mismatch is located in a middle position (paragraph 12).

Regarding claim 19, Gingeras teaches that the perfect match probes target transcripts from non-repetitive sequence of the genome (paragraph 13).

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Regarding claim 20, Gingeras teaches a method for comparing the small RNA transcriptional activity of two biological samples comprising:

- (a) obtaining a first small RNA sample (paragraph 7)
- (b) obtaining a second small RNA sample (paragraphs 7 and 14, which teach use of different samples; see also claim 30 where two samples are used)
- (c) hybridizing the first and second small RNA samples or nucleic acids derived from the first and second small RNA with an oligonucleotide probe array wherein the oligonucleotide probe array contains at least 10,000 perfect match (PM) probes, each of the perfect match probes targeting a different transcript sequence from a region of a genome (paragraph 7)
- (d) determining, for each of the first and second sample, that a genomic sequence is transcribed if the probe against the genomic sequence is hybridized with a target (paragraph 7)
- (e) comparing the transcribed sequences between the first and second sample (see paragraph 14).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 30 fill in of copending Application No. 10/316,518 in view of Wassarman et al. (Genes & Development (2001) 15: 1637-1651).

Claims 1-19 and 30 of the '518 application are drawn to methods of determining genomic transcriptional activity based on hybridization of one or two polyA+ RNA samples to high density oligonucleotide arrays. Claims 1-19 and 30 of the '518 application correspond exactly to the instant claims 1-20, respectively, with the exception that polyA+ RNA is recited in the '518 claims rather than the instantly claimed small RNAs.

Wassarman teaches identification of novel small RNAs using an unspecified high-density oligonucleotide array (see abstract, page 1638 and page 1649). Wasserman expressly states, "We used the high conservation of small RNAs among closely related bacterial species, as well as analysis of transcripts detected by high-density oligonucleotide probe arrays, to predict the presence of novel small RNA genes in the intergenic regions of the Escherichia coli genome" (abstract).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to apply the method of the '518 application to small RNAs. As noted above, the '518 claims only differ from the instant claims in the particular target – polyA+ RNA in the '518 application versus small RNA in the instant application. Since Wasserman taught that high-

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density oligonucleotide arrays were useful for detecting/monitoring small RNAs (see abstract and page 1638), the ordinary practitioner would have been motivated to apply the method of the '518 application to this other type of RNA, thereby extending the applicability of the method.

This is a provisional obviousness-type double patenting rejection.

8. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 30 fill in of copending Application No. 11/234,508 in view of Wassarman et al. (Genes & Development (2001) 15: 1637-1651).

Claims 1-19 and 30 of the '508 application are drawn to methods of determining genomic transcriptional activity based on hybridization of one or two polyA+ RNA samples to high density oligonucleotide arrays. Claims 1-19 and 30 of the '508 application correspond exactly to the instant claims 1-20, respectively, with the exception that polyA+ RNA is recited in the '508 claims rather than the instantly claimed small RNAs.

Wassarman teaches identification of novel small RNAs using an unspecified high-density oligonucleotide array (see abstract, page 1638 and page 1649). Wasserman expressly states, "We used the high conservation of small RNAs among closely related bacterial species, as well as analysis of transcripts detected by high-density oligonucleotide probe arrays, to predict the presence of novel small RNA genes in the intergenic regions of the Escherichia coli genome" (abstract).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to apply the method of the '508 application to small RNAs. As noted above, the '508 claims only differ from the instant claims in the particular target – polyA+ RNA in the '508

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application versus small RNA in the instant application. Since Wasserman taught that high-density oligonucleotide arrays were useful for detecting/monitoring small RNAs (see abstract and page 1638), the ordinary practitioner would have been motivated to apply the method of the '508 application to this other type of RNA, thereby extending the applicability of the method.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marker et al. (Current Biology (2002) 12: 2002-2013), Rosenow (US 2002/0106644 A1), and Rabani et al. (US 2004/0161741 A1) are cited as references of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Patent Examiner
Art Unit 1637

amb


JEFFREY FREDMAN
PRIMARY EXAMINER
7/28/02